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# Strategies to Eliminate Inequity in PrEP Services in the US South and Rural Communities

**Emiko Kamitani, PhD, MPH, MS, RN*** **[Behavioral Scientist]**,
Division of HIV Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia, U.S. 30329-4027

**Yuko Mizuno, PhD [Behavioral Scientist]**,
Division of HIV Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia, U.S. 30329-4027

**Linda J. Koenig, PhD, MS [Senior Advisor]**
Division of HIV Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia, U.S. 30329-4027

## Abstract

Inequity in PrEP care in the US South and rural communities is likely attributed to Social Determinants of Health and structural issues beyond individuals' control. We describe three approaches to modify PrEP care practice models to make access easier – "normalizing", "digitalizing", and "simplifying". "Normalizing" approaches are defined as practice models where medical providers who have access to PrEP candidates prescribe PrEP routinely (e.g., primary care providers, community pharmacists); these approaches are found to be highly applicable in real-world settings. Telehealth and other dHealth tools are examples of "digitalizing" PrEP and their use has been increasing rapidly since the COVID-19 pandemic. "Simplifying" PrEP care (e.g., with HIV self-testing, on-demand PrEP) is highlighted in the most recent World Health Organization PrEP guideline. Identifying, implementing, and scaling up these new strategies can allow PrEP candidates to access it, potentially addressing inequities and promoting HIV risk reduction in the US South and rural communities.

### Keywords

Pre-exposure prophylaxis; HIV; Inequity; US South; Rural; Social Determinants of Health

*Corresponding author: Emiko Kamitani, ybo9@cdc.gov.

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## Background

HIV pre-exposure prophylaxis (PrEP) is a key tool to ending the global HIV and AIDS epidemic by 2030 (Department of Health and Human Services, 2023; United Nations, 2023). More than 3.8 million people had initiated oral PrEP globally by the end of 2022 (AIDS Vaccine Advocacy Coalition [AVAC], 2023). Of these, about 10% (363,148) were in the U.S.; however, this covers only 30% of 1.2 million U.S..individuals who have indications for PrEP (hereafter referred to as PrEP candidates; (Centers for Disease Control and Prevention [CDC], 2023c). Moreover, in the U.S., PrEP coverage was uneven across geographic areas and among racial and ethnicity groups. The recently released CDC HIV Surveillance Report revealed substantial differences by race and ethnicity; while 78% of White PrEP candidates were prescribed PrEP, the coverage was as low as 11% for Black/African American persons, 21% for Hispanic/Latino persons and 12% for persons of other races (CDC, 2023c). There remains significant room for improvement.

Several reasons for the low PrEP uptake include lack of insurance, stigma, and poverty, but one major cause is the lack of access to healthcare providers who are knowledgeable about and willing to prescribe PrEP (Storholm, Ober, et al., 2021). The slow growth of PrEP initiation globally is the existence of “PrEP deserts”, locations defined by an hour or more round-trip drive required to access PrEP services (Siegler, Bratcher, et al., 2019). US-based studies found that the PrEP desert status is strongly associated with the Southern U.S. and rurality (Siegler, Bratcher, et al., 2019). This association is consistent with the fact that only 20% of PrEP candidates in the U.S. South were prescribed PrEP in 2020 (29% for Northeast, 21% for Midwest, 20% for West) (CDC, 2021a). The lack of PrEP coverage in the U.S. South may, in part, explain why more than half of the new HIV infections in the U.S. continue to occur in the South (CDC, 2023b; HIV.gov, 2022). A previous systematic review found that gay, bisexual and other men who have sex with men (MSM) living in the U.S, South were more willing to use PrEP but were not on PrEP compared with MSM living elsewhere (Kamitani, Wichser, et al., 2023). All these findings suggest that inequity in PrEP care is likely attributed to Social Determinants of Health (e.g., social environment including poverty and discrimination) and structural issues beyond individuals’ control (CDC, 2022). The findings also point to the need for innovative and unique system-level or structural interventions to improve PrEP care access, especially in PrEP deserts, to eliminate inequity in PrEP care.

## Novel and Promising Interventions

This commentary describes existing but novel and promising programs and interventions to potentially improve PrEP access in the U.S. South and rural communities. We identify three approaches to modify PrEP care practice models to make access easier – “normalizing”, “digitalizing”, and “simplifying”. We define “normalizing” PrEP care as practice models where healthcare providers who have access to PrEP candidates prescribe PrEP routinely as a standard of care. We discuss the types of routine care settings (e.g., primary care clinics, syringe service programs [SSP], community pharmacies) in which providers have been prescribing PrEP. “Digitalizing” PrEP care (e.g., telePrEP) is an approach that uses technology meant to improve PrEP uptake and persistence and has rapidly grown during

the COVID-19 pandemic, and we discuss how this approach can be maintained and further expanded to deliver PrEP care to those in the PrEP deserts. Finally, we discuss "simplifying" PrEP care by reviewing World Health Organization (WHO) and the U.S. Public Health Service PrEP clinical practice guidelines and highlighting ways to streamline PrEP uptake (e.g., on-demand PrEP, injectable PrEP) and HIV testing for PrEP care (e.g., with HIV self-testing, mail-in testing). By exploring these approaches in more depth, this commentary aims to identify and call for the implementation and scale-up of strategies that are likely to increase PrEP uptake among persons living in the southern U.S. and rural areas.

## Normalizing PrEP Care

Normalizing PrEP Care Primary care settings, sexually transmitted infection (STI) clinics, and HIV testing sites have been identified as effective, appropriate places to screen people for PrEP eligibility (Chan et al., 2021; Schaffer et al., 2022; Storholm, Siconolfi, et al., 2021). Whereas screening for PrEP at these health care settings is acceptable and feasible (Chan et al., 2021; Storholm, Siconolfi, et al., 2021), prescribing PrEP in these healthcare or non-healthcare settings is still challenging. PrEP care may be considered by some providers as a part of HIV specialty care, and some believe that PrEP care should be practiced by HIV specialists. This "purview paradox" – regarding who should prescribe PrEP – is still being debated (Krakower et al., 2014; Mizuno et al., 2022). HIV specialists are more familiar with antiretroviral treatment, but primary care providers have access routinely to and may have established trusting relationships with PrEP candidates.

To determine if there are any evidence-based interventions that improve PrEP access by prescribing at primary care settings, we searched CDC's Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention (the *Compendium*) (CDC, 2023d). As of September 2023, 13 Best Practices (i.e., interventions and strategies with the strongest efficacy [evidence-based or EBI] or some evidence [evidence-informed or EI]) have been identified in the Compendium to improve PrEP uptake and persistence. One of these Best Practices is the PrEP and PEP Public Health Detailing Campaign for Cisgender and Transgender Women (Wahnich et al., 2021), a structural PrEP intervention to improve PrEP access. In this intervention, trained health department representatives introduced an "Action Kit" including U.S, Public Health Service's PrEP clinical practice guideline to 1,348 medical providers at women's health clinics in New York City. The study showed that the percentage of medical providers who prescribed PrEP increased significantly with this intervention. This intervention focused specifically on healthcare providers for women because of concerns about the underutilization of PrEP among women in New York City. However, this intervention may be also applicable to other locations and populations. The Public Health Detailing program has been implemented to promote essential preventive and disease management practices (e.g., influenza vaccination, cancer screening) in various high mortality areas in New York City since 2003 and has improved practice among healthcare providers (Larson et al., 2006; New York City Department of Health and Mental Hygiene, 2023). The success of this intervention strategy with various focus populations (e.g., healthcare providers for people who have certain disease risk factors or live in high mortality areas) suggests that the PrEP Public Health Detailing Campaign may be adoptable and feasible in other places such as in the U.S. South and rural communities and with

healthcare providers of other key populations identified in the National HIV/AIDS Strategy (e.g., youth aged 13–24 years and people who inject drugs [PWID]) (The White House, 2021).

For improving PrEP access among PWID, Project Sexual Health Equity (SHE) has integrated PrEP care into a SSP (Roth et al., 2021). The intervention did not meet the PRS Best Practice's criteria because no PRS relevant outcome was reported in this implementation study, but the authors found that integrating PrEP into SSP services was feasible and acceptable among 95 study participants who were cisgender women and inject drugs in Philadelphia (Roth et al., 2021). Integration of PrEP into care settings that PWID use routinely and where trust is likely to be present may increase PWID's access to PrEP (Bachhuber et al., 2018). The success of Project SHE, which integrates PrEP care into a fixed SSP may inform how such an approach can be used in outreach or more mobile SSP settings.

The Infectious Disease Elimination Act (IDEA) Exchange in Miami provides comprehensive SSPs with health care including buprenorphine treatment and has implemented PrEP care in outreach settings (Bartholomew et al., 2022; H. Tookes, personal communication, April 4, 2023). Prior to the implementation, the researchers assessed acceptability and feasibility of the PrEP program among 30 Black or African American PWID and found that PrEP care at mobile SSP settings was feasible and acceptable and would help to address transportation, cost and stigma experienced by Black or African American PWID at traditional healthcare settings (Bartholomew et al., 2022). As of April 2023, the IDEA Exchange has pilot tested on-demand PrEP and engaged 68 people in their PrEP services (H. Tookes, personal communication, April 4, 2023). The approach used in these projects might help reach more PWID, particularly as most of the HIV outbreaks among PWID have been occurring in rural areas such as in Indiana (Conrad et al., 2015) and West Virginia (Atkins et al., 2020).

One Tent Health, which is not an SSP but provides mobile HIV testing, launched PrEP "on-the-spot" (Schaffer et al., 2022). This program has provided mobile free HIV testing in areas with high HIV prevalence within Washington, D.C. since 2017, and had established good rapport with the community before the PrEP service was implemented (Straube, 2020). At the testing sites, PrEP candidates were provided a 10-day starter pack of PrEP along with contacts at clinics for follow-up blood work and prescriptions to take home (Straube, 2020). These kinds of outreach programs, with well-established presence and rapport with the communities, may be important for reaching and increasing PrEP uptake among PrEP candidates (Schaffer et al., 2022). Moreover, HIV testing sites may be one of the most relevant places to reach PrEP candidates.

The recently released 2021 Annual HIV Testing Report noted that HIV testing sites in non-healthcare settings had the highest HIV positivity rate (0.8%) among CDC-funded HIV tests conducted in the U.S. (CDC, 2023a). The positivity rate was higher than other site types such as STI clinics (0.5%), community settings including schools/educational facilities or bar/club/adult entertainment (0.5%), non-healthcare correctional facilities (0.4%), community health centers (0.3%), emergency departments (0.3%), and healthcare

correctional facilities (0.2%) (CDC, 2023a). This data suggests that HIV testing sites may have more chances to reach people with HIV risk factors and provide HIV prevention before seroconversion. Further, One Tent Health is following the Status Neutral model of HIV prevention and care, where HIV testing serves as a gateway for referral to either HIV care (if a positive test is confirmed) or PrEP (if tested HIV negative) (CDC, 2023e; Myers et al., 2018). This care model is especially pertinent for HIV testing sites.

Positive findings from the PrEP and PEP Public Health Detailing Campaign for Cisgender and Transgender Women (Wahnich et al., 2021) and Project SHE (Roth et al., 2021) suggest that better PrEP access may be achieved when providers, who have established trusted relationships with patients who are PrEP candidates, proceed and prescribe PrEP directly instead of referring their patients who are candidates for PrEP to HIV specialists. To expand PrEP services, the Health Resources and Services Administration (HRSA) Bureau of Primary Health Care (BPHC) is implementing the Ending the HIV Epidemic (EHE) – Primary Care HIV Prevention (PCHP) project. This project has funded health centers in the 57 EHE geographic jurisdictions throughout the U.S. since 2020 to implement PrEP service in primary health care settings (HRSA, 2023c). Among the 302 PCHP-funded health centers (i.e., 195 in fiscal year [FY] 2020, 107 in FY 2021), 52,477 individuals were prescribed PrEP in addition to over 1.7 million HIV tests provided in primary care settings (K. Argueta, personal communication, April 7, 2023). The project has funded an additional 64 health centers in FY 2022 and is planning to fund up to 140 health centers in FY 2023 (Department of Health and Human Services, 2022; HRSA, 2023b). Such federal funds and support may further promote primary care providers' PrEP prescribing and improve PrEP access in the U.S..

Some people living in the U.S. South or rural communities may not have easy access to primary care providers (HRSA, 2023d). To resolve this issue, pharmacist prescribers may be helpful. Indian Health Services has implemented a pharmacist-led PrEP clinic and reported expansion of PrEP access among tribal communities (Vu, 2022). CDC identified community pharmacists as a profession to provide critical health services during the COVID-19 pandemic (Strand et al., 2020) because more than 90% of individuals in the U.S. live less than 5 miles from a community pharmacy (Qato et al., 2017). Moreover, individuals in the U.S. visit their community pharmacist 12 times more often than their primary care provider (EnlivenHealth, 2023). Because of the geographical advantage, community pharmacists may be able to fill the service gaps in the areas considered PrEP deserts, especially in the U.S. South and rural communities, and improve PrEP access in areas where primary or routine healthcare providers are in short supply. Our recent systematic review found that pharmacist prescribers working within a collaborative practice agreement (CPA) is a highly applicable approach for implementation due to its ability to reach the focus population, positive effects on PrEP care delivery, appeal to clients and implementation staff, and less-challenging implementation procedures (Kamitani, Mizuno, et al., 2023).

## Digitalizing PrEP Care

Digitalizing PrEP Care During the COVID-19 pandemic, digitalization of health care has been adopted to deliver health care in personal spaces to minimize the exposure

to COVID-19, and telePrEP was encouraged by CDC and HRSA during the pandemic (CDC, 2020; HRSA, 2022b). Post-COVID-19, maintaining or expanding telePrEP may help individuals who are struggling to find time or transportation to travel to meet the monitoring requirements, especially those living in the U.S. South or rural communities (HRSA, 2022a; Hubach et al., 2017; Sullivan et al., 2019; Whitfield et al., 2018). Our recent systematic review found that telePrEP has high applicability for PrEP care and would be appropriate for implementation under real-world conditions (Kamitani, Mizuno, et al., 2023). For example, Player et al. (2022) implemented telePrEP among 20 individuals in North Charleston, South Carolina and found that more than a third of participants were unlikely to have received PrEP without the telePrEP program. After successful implementation of PrEP in a Southern urban area, the telePrEP intervention is now expanded in other southern rural areas (Player et al., 2022). Since April of 2021, the telePrEP project had received 116 referrals from across the region, 67 participants were enrolled, and about 40 initial video visits were conducted (M. Player, personal communication, May 11, 2023). The telePrEP project has successfully reached populations that could benefit from PrEP (e.g., 30% reported not having medical insurance) and a larger and more diverse population in Southern rural and under-resourced areas compared to their pilot study (M. Player, personal communication, May 11, 2023).

Our review also examined the applicability of how telePrEP is delivered. While the Telehealth in Washington intervention (Stekler et al., 2018) was accessed at a community-based clinic, telePrEP in South Carolina (Player et al., 2022) and PrEPTECH (Refugio et al., 2019) were accessed from home (or unspecified places other than fixed places). We found that telePrEP accessed from home had higher applicability compared to when accessed from a community-based clinic (Kamitani, Mizuno, et al., 2023). Accessing from home may be more appropriate than from fixed places (e.g., community-based organizations, healthcare clinics) for implementation under real-world conditions, but it is important to make sure that people have the capacity to use telePrEP (e.g., digital device, internet) and are provided assistance to access telePrEP when needed. TelePrEP should be utilized to eliminate inequity in PrEP service and should not be a further cause of healthcare disparity or digital divide.

Silicon Valley startups found digital PrEP care an optimistic business opportunity. In 2018, Nurx, a telemedicine and pharmacy delivery startup, launched a unique and innovative telePrEP program providing 100% web- and app-based PrEP services (Nurx, 2023). They offer counseling via web or mobile app, mail-in testing, and PrEP home-delivery services without any in-person office or lab visits (Hughes et al., 2021; Nurx, 2023). Such web-based PrEP services without in-person office or lab visits may enable individuals living in states that allow it to receive PrEP services without traveling. Furthermore, the study assessed experiences of Nurx users and reported reduced initial skepticism and satisfaction among users once they received the service; they mentioned that barriers to PrEP access were erased as embarrassment and discrimination were minimized (Hughes et al., 2021).

HRSA has had an active role in healthcare for persons in rural areas and has expanded their telehealth program. For the first time since its inception in 1987, HRSA’s Federal Advisory committee, the National Advisory Committee on Rural Health and Human

Services (NACRHHS), selected HIV upon which to focus its deliberations at the NACRHHS annual meeting in 2020 (HRSA, 2023a; Jackson & Kosogof, 2020). As a result of the annual meeting and responses to the EHE initiative, HIV Prevention and Treatment Challenges in Rural America: Policy Brief and Recommendations to the Secretary was released (NACRHHS, 2020b). The recommendation emphasized the expansion of the use of telehealth to increase access to HIV services and reduce stigma in rural areas (NACRHHS,2020a). In order to do so, the recommendations focused on enhancing federal funding to increase and improve capacity building for HIV services in rural areas (including telehealth and PrEP) along with providing more technical assistance (NACRHHS, 2020a). Those actions demonstrate that HRSA as well as other federal agencies are focusing on increasing telehealth broadly to improve HIV care in rural areas, by addressing policies, technologies, and programs.

To expand telePrEP throughout the U.S., CDC has been providing funds and a multi-session training program for integrating telePrEP into healthcare. Through CDC's funding PS19–1906: Strategic Partnership and Planning to Support Ending the HIV Epidemic in the United States, the National Alliance of State and Territorial AIDS Directors (NASTAD) was contracted to provide technical assistance to 57 EHE priority jurisdictions (CDC, 2019; NASTAD, 2023a). As a part of the program, NASTAD's TelePrEP Learning Collaborative was developed to scale up PrEP access, meet goals of EHE, and support PrEP maintenance while adhering to then public health recommendations for social distancing for COVID-19 exposure (NASTAD, 2021; NASTAD, 2023b). Following the completion of the collaborative, NASTAD launched a self-paced, online learning series to assist jurisdictions in implementing a telePrEP program to expand, strengthen, or develop a telePrEP program at any health department, Community-Based Organization, or community health centers (NASTAD, 2023b). Such federal funds and technical assistance would help expand telePrEP throughout the U.S. and might increase PrEP access, reduce the cost of providing PrEP care, and reduce health inequities across geographic settings and populations (NASTAD, 2021).

## Simplifying PrEP Care

Simplifying PrEP Care In 2021, the WHO released a new technical brief to update and supplement its previous PrEP guidelines to simplify PrEP services (WHO, 2022). The simplified PrEP care model may be applicable in places such as Sub-Saharan Africa but can also be considered to improve PrEP care in the U.S. South or rural communities that may encounter similar issues that Sub-Saharan Africa has been experiencing (e.g., establishing systems to link generally otherwise healthy people to ongoing PrEP services, maintaining PrEP adherence, experiencing HIV stigma) (Irungu & Baeten, 2020). The strategies are designed to remove some structural barriers that people in rural or remote communities experience and to allow more people to access PrEP care and uptake PrEP.

The new WHO guideline endorses HIV self-testing for PrEP care (WHO, 2022). The U.S, Public Health Service PrEP clinical practice guideline indicates that an HIV oral swab-based self-test is acceptable only if there are no other options. However, a mail-in test (i.e., a specimen collection kit that is sent to a lab for testing) is recommended in the U.S, guideline even though it is not approved by Food and Drug Administration (FDA)

as of September 2023 (CDC, 2021b). PrEP@Home, an intervention which implemented mail-in HIV, STI, and creatine testing among 58 MSM in urban areas, showed high acceptance of mail-in testing (Siegler, Mayer, et al., 2019), and high potential applicability for implementation under real-world conditions (Kamitani, Mizuno, et al., 2023). Siegler and colleagues are currently conducting a randomized controlled trial, ePrEP, to test the efficacy of mail-in testing and home-based care, a tailored mobile phone app, and interactive video consultations among nonurban young MSM to increase PrEP initiation and retention (Siegler, Brock, et al., 2019). Previous studies report discomfort in receiving PrEP services due to HIV stigma, racism, sexism, and homophobia experienced at healthcare sites (Chasco et al., 2021; Mayer et al., 2020; Peng et al., 2018). Mail-in testing may reduce such discomfort and encourage people to continue receiving PrEP care.

Additionally, the new WHO guideline highlights that on-demand PrEP can be used to prevent sexually acquired HIV by cisgender men and transgender persons whose assigned sex at birth was male (World Health Organization, 2022). The latest PrEP clinical practice guideline for the U.S. does not recommend on-demand PrEP (CDC, 2021b) due to a lack of available evidence at the time of publication. Since WHO and CDC released these updates, the Agence Nationale de Recherches sur le SIDA et les hépatites virales (ANRS) PREVENIR (“prevent” in French) conducted a prospective observational cohort study after the success of an efficacy trial of on-demand PrEP (the ANRS Intervention Préventive de l’Exposition aux Risques avec et pour les Gays [IPERGAY]) and published updated data with 3,056 patients followed-up for a median of 22 months (Molina et al., 2022). The observational cohort study continued to find evidence for the efficacy of on-demand PrEP – that is, no difference between participants using daily PrEP and those using on-demand PrEP. Based on the updated findings of the ANRS PREVENIR trial (Molina et al., 2022) and new WHO guidelines (World Health Organization, 2022), evidence for the efficacy of on-demand PrEP is growing. However, on-demand PrEP requires planning (i.e., taking 2 pills 2–24 hours before sex) and follow-up doses (i.e., a pill 24 hours after the first dose, another pill 24 hours after the second dose), and WHO recommends it only to prevent sexually acquired HIV among cisgender men and transgender persons whose assigned sex at birth was male.

For women, the WHO has recommended the first simplified PrEP regimen - the dapivirine vaginal ring (DPV-VR) since January 2021 (WHO, 2021). This long-acting (monthly) HIV prevention method, specifically developed for women, has been recommended for use by those who are at substantial risk for HIV infection such as serodiscordant couples and individuals who engaged in high-risk sexual behaviors (WHO, 2021). DPV-VR sought approval for use in the U.S. but voluntarily withdrew from FDA consideration in December 2021 after receiving feedback that current epidemiologic data and the prevention landscape for women in the U.S, are unlikely to support U.S, approval (Clinicalinfo.HIV.gov, 2022). In the same month, FDA approved the first injectable PrEP, cabotegravir (Apretude) injections, to lower the risk of sexually acquired HIV through sex for all populations including women (FDA, 2021). The every-other-month injectable formulation may help those who struggle to take daily PrEP. Simplified PrEP care and more choices on dosing regimens and methods can increase access and persistence for those in need of PrEP services.

## Conclusion

By normalizing, digitalizing, and simplifying PrEP care, more people in need of PrEP will gain access to it. The evidence reviewed here provides a strong foundation for action and requires a commitment to scaling up new structural approaches to getting PrEP to those who do not currently have access, especially those who live in regions characterized as PrEP deserts. These approaches will likely require additional training for providers, and technical assistance to both providers and patients, which are important considerations for implementing and integrating these approaches into standard practice. However, implementing and scaling up these approaches can allow more people in need of PrEP to access it, addressing inequities and promoting PrEP use. These strategies will help reduce the geographic disparities experienced by those in the Southern U.S, and rural communities as well as ethnic disparities experienced by Black/African American and other racial and ethnic minorities to achieve EHE goals.

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